UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BARBARA TRUSS, NATALIA GOLSON, JACK KILGORE, and GABRIELA PETTIBONE, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

BAYER HEALTHCARE PHARMACEUTICALS INC., a Delaware corporation; BAYER HEALTHCARE LLC, a Delaware limited liability company; BEIERSDORF, INC., a Delaware corporation; and BEIERSDORF NORTH AMERICA, INC., a Delaware corporation,

Defendants.

OPINION AND ORDER

21 CV 9845 (VB)

Briccetti, J.:

Plaintiffs Barbara Truss, Natalia Golson, Jack Kilgore, and Gabriela Pettibone bring this putative class action against defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare LLC, Beiersdorf, Inc., and Beiersdorf North America, Inc., arising out of defendants' allegedly deceptive labeling of Coppertone Water Babies (SPF 50) sunscreen as hypoallergenic and free of oxybenzone, when in fact it contains benzophenone. Plaintiffs assert claims for deceptive practices under New York General Business Law Section 349 and the California Consumer Legal Remedies Act (the "deceptive practices claims"), false advertising under New York General Business Law Section 350 and the California False Advertising Law (the "false advertising claims"), unfair competition under the California Unfair Competition Law, and common law claims for breach of express warranty, breach of implied warranty of merchantability, and unjust enrichment (the "common law claims").

Now pending is defendants' motion to dismiss the second amended complaint ("SAC") under Rule 12(b)(6) and, solely with respect to plaintiffs' request for injunctive relief, Rule 12(b)(1). (Doc. #48).

For the following reasons, the motion is GRANTED.

BACKGROUND

For the purpose of the ruling on the motion, the Court accepts as true all well-pleaded allegations in the SAC and draws all reasonable inferences in plaintiffs' favor, as summarized below.

Defendants manufacture and distribute Coppertone Water Babies (SPF 50) sunscreen (the "Product"). Coppertone has been sold since 1944 and is a well-known sunscreen brand in the United States and abroad. Today, "thousands of retail locations throughout the United States" sell the Product. (SAC ¶ 21).

Plaintiffs are citizens of California and New York who allegedly purchased the Product in 2021 and used it on themselves and their families.

Plaintiffs allege the Product, although marketed as "hypoallergenic," "dermatologically tested," and "gentle on baby's skin," contains benzophenone, "a known mutagen, carcinogen, allergen, and endocrine disruptor that is not FDA approve[d] as an active ingredient in sunscreen products." (SAC ¶¶ 1–2). Benzophenone is allegedly "a hazardous impurity and degradation product of octocrylene," which is an active ingredient in the Product. (SAC ¶ 41). Plaintiffs determined the Product contains benzophenone by commissioning independent third-party testing.

Plaintiffs allege benzophenone "is associated with a wide range of toxicities, including genotoxicity, carcinogenicity, and endocrine disruption" and is not hypoallergenic. (SAC ¶¶ 37,

38). Benzophenone also appears on the California Proposition 65 list, and therefore, California requires manufacturers to warn consumers when a product contains benzophenone.

Plaintiffs claim the presence of benzophenone renders the Product mislabeled, misbranded, adulterated, and defective. They contend defendants know the Product contains benzophenone because of prior litigation, yet fail to include benzophenone in the Product's ingredients list. Plaintiffs further allege the presence of benzophenone renders defendants' representation and labeling of the Product as "Hypoallergenic & Gentle" and "free of oxybenzone" false and misleading. (SAC ¶¶ 30, 35). Plaintiffs claim they and the putative class believed, based on defendants' representations, the Product was hypoallergenic, gentle, safe for babies' skin, and "free from harmful toxins, contaminants, undisclosed chemicals, and undisclosed allergens." (SAC ¶ 36).

Plaintiffs claim they would not have purchased the Product, or would have paid significantly less for it, had they been aware it contained benzophenone. Each plaintiff alleges they or their relatives experienced skin ailments including burning, flaking, itching, and dryness after applying the sunscreen.

DISCUSSION

I. Rule 12(b)(6) Standard of Review

In deciding a Rule 12(b)(6) motion, the Court evaluates the sufficiency of the complaint under the "two-pronged approach" articulated by the Supreme Court in Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009).[1] First, a plaintiff's legal conclusions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not entitled to the

[1] Unless otherwise indicated, case quotations omit all internal citations, quotation marks, footnotes, and alterations.

assumption of truth and thus are not sufficient to withstand a motion to dismiss. Id. at 678; Hayden v. Paterson, 594 F.3d 150, 161 (2d Cir. 2010). Second, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 556 U.S. at 679.

To survive a Rule 12(b)(6) motion, the complaint's allegations must meet a standard of "plausibility." Ashcroft v. Iqbal, 556 U.S. at 678; Bell Atl. Corp. v. Twombly, 550 U.S. 544, 564 (2007). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id. (quoting Bell Atl. Corp. v. Twombly, 550 U.S. at 556).

"In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 111 (2d Cir. 2010). "Where a document is not incorporated by reference, the court may nevertheless consider it where the complaint relies heavily upon its terms and effect, thereby rendering the document integral to the complaint." Id.

II. Federal Preemption

Defendants argue plaintiffs' claims are expressly preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 301 et seq.

The Court agrees plaintiffs' deceptive practices, false advertising, unfair competition, and common law claims are preempted to the extent they arise from defendants' alleged failure to disclose the presence of benzophenone in the Product.

A. Legal Standard

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000). Thus, "[w]here state and federal law directly conflict, state law must give way." PLIVA, Inc. v. Mensing, 564 U.S. 604, 617–18 (2011). In determining whether federal preemption applies, "[c]ourts must 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act.'" Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 660 (S.D.N.Y. 2017) (quoting Wyeth v. Levine, 555 U.S. 555, 565 (2009)).

"Express preemption is present when Congress's intent to preempt state law is explicitly stated in the statute's language." In re PepsiCo., Inc., Bottled Water Mktg. & Sales Pracs. Litig., 588 F. Supp. 2d 527, 530 (S.D.N.Y. 2008). To determine whether Congress intended to preempt state law, courts consider whether "the statute contains an express pre-emption clause." CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993).

B. FDCA Preemption

Congress passed the FDCA "in 1938 as part of a comprehensive federal regulatory scheme to protect consumers from fraud or misrepresentation in the sale of food, drugs, and cosmetics." Critcher v. L'Oreal USA, Inc., 2019 WL 3066394, at *2 (S.D.N.Y. July 11, 2019), aff'd, 959 F.3d 31 (2d Cir. 2020). "In doing so, Congress intended to create a national and uniform regulatory scheme, . . . which up until the FDCA's passage, had been subject to the disparate laws of the states." Young v. L'Oreal, Inc., 2021 WL 2295625, at *2 (S.D.N.Y. May 20, 2021), report and recommendation adopted sub nom. Young v. L'Oreal USA, Inc., 2021 WL 2292341 (S.D.N.Y. June 4, 2021); see also Goldstein v. Walmart, Inc., 2022 WL 16540837, at *5–7 (S.D.N.Y. Oct. 28, 2022).

Under the FDCA, the U.S. Food and Drug Administration ("FDA") regulates the sale of over the counter ("OTC") drugs in the United States, including sunscreen. 21 U.S.C. § 301 et seq; 21 C.F.R. § 352.1. The FDA promulgates a "monograph," which is "a detailed regulation . . . for each therapeutic class of OTC drug products," after a notice-and-comment process. See Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin., 710 F.3d 71, 75 (2d Cir. 2013). By following a monograph, manufacturers seeking to sell a new OTC drug in interstate commerce may qualify for an FDA determination that a medication is generally recognized as safe and effective ("GRASE") while bypassing individualized review. Id. Monographs set "the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provide[] the conditions under which each active ingredient is" GRASE. Id.

Congress enacted Section 505(g) of the FDCA through the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which established the most recent monograph governing sunscreen, effective March 27, 2020 (the "2020 Monograph"). CARES Act § 3854, Pub. L. No. 116–136, 134 Stat. 281 (2020). The 2020 Monograph permits sunscreens to be formulated using sixteen specified active ingredients below certain thresholds. 21 C.F.R. § 352.10. Further, the 2020 Monograph regulates the content of sunscreen labels. For example, sunscreen labels must contain information regarding the product's effectiveness and water resistance, describe its uses, and specify applicable warnings. Id. § 352.52. The 2020 Monograph also establishes formulation and testing guidelines, including requirements governing the frequency at which sunscreen products must be tested and the number of test subjects. Id. §§ 352.70–352.77. Sunscreen products that comply with the 2020 Monograph and corresponding FDA regulations are deemed GRASE by the FDA. Id. § 352.1(a).

The FDCA contains an express preemption provision for conflicting state laws governing

OTC drugs, including sunscreen; it prohibits states from establishing any requirement related to the regulation of an OTC drug "that is different from or in addition to, or that is otherwise not identical to" a requirement under the FDCA. 21 U.S.C. § 379r(a); Critcher v. L'Oreal USA, Inc., 959 F.3d at 35 (considering preemption in the similar context of cosmetics and observing that "to ensure . . . various federal requirements are not obstructed by state law . . . Congress added to the FDCA an expansive preemption provision"). Indeed,

> the FDCA preempts not only those state laws that are in conflict with it (i.e., any law that is "different from" the FDCA), but also any state law that provides for . . . requirements that are not exactly the same as those set forth in the FDCA and its regulations (i.e., any law that is "in addition to" the FDCA).

Id. at 35–36; see also Canale v. Colgate-Palmolive Co., 258 F. Supp. 3d 312, 320 (S.D.N.Y. 2017) ("Where federal law specifically regulates the subject matter of a plaintiff's state law claims, and those claims seek to impose requirements not identical to federal requirements, those state law claims are preempted.").

C. Application

Plaintiffs' claims are expressly preempted by FDCA labeling requirements for sunscreen, to the extent they result from the Product label's omission of benzophenone.

Although plaintiffs argue their "claims rely on specific violations of the FDCA and are therefore identical to FDCA requirements," such that plaintiffs "are not asking Defendants to undertake any additional [labeling] steps" (Doc. #53-1 ("Pl. Opp.") at 3–4), all of plaintiffs' claims are premised on the allegation that the Product contains benzophenone that is not disclosed on the Product's label. Even accepting this allegation as true, as the Court must at this stage, the Court concludes the relevant provisions of the FDCA and the 2020 Monograph preempt such claims.

First, plaintiffs are incorrect that defendants are required to disclose the presence of

benzophenone in the Product. In the SAC, plaintiffs indicate that benzophenone is a byproduct of octocrylene, an active ingredient in the Product.[2] The FDA promulgated general labeling requirements for all OTC drugs, including sunscreen, under which manufacturers must disclose an OTC drug's active and inactive ingredients. 21 C.F.R. § 201.66(c). The FDCA defines "active ingredient" as:

> any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

Id. § 201.66(b)(2). It further defines an "inactive ingredient" as "any component other than an active ingredient." Id. § 201.66(b)(8). A "component" is "any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product." Id. § 210.3(3) (emphasis added).

Here, plaintiffs do not allege defendants manufactured the Product to contain benzophenone. Thus, benzophenone is not an active or inactive ingredient in the Product, as those terms are defined under the FDCA, and federal law does not require it to appear on the Product's label. In fact, the FDA allows sunscreens to be formulated with the active ingredient "Octocrylene up to 10 percent," and does not require disclosure that octocrylene may degrade into benzophenone. 21 C.F.R. § 352.10(l); (see SAC ¶ 22). Because the Court concludes the FDCA does not mandate disclosure of degradation byproducts (like benzophenone), the labeling duties plaintiffs seek to impose are additional to those imposed by the FDCA. Critcher v.

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[2] Although in the SAC, plaintiffs initially allege "the source of the Product's benzophenone contamination is unclear" (SAC ¶ 35 n. 14), this is belied by their contrary allegations throughout the SAC that benzophenone is a degradation byproduct of octocrylene. (SAC ¶¶ 37 n. 15, 41, 172; Id., Ex. B, at 2).

L'Oreal USA, Inc., 959 F.3d at 37. Plaintiffs' claims are "exactly what the FDCA does not permit." Id. Permitting such claims to move forward "would lead precisely to the patchwork of inconsistent packaging regulations that Congress sought to prevent." Goldstein v. Walmart, Inc., 2022 WL 16540837, at *12 (noting that if individuals believe the FDA has reached an incorrect conclusion, they can engage in a citizen petition).

Accordingly, all of plaintiffs' deceptive practices, false advertising, unfair competition, and common law claims must be dismissed to the extent they are based on the Product's lack of disclosure of the byproduct benzophenone.

III. Plaintiffs' Claims Arising from "Free of Oxybenzone" and "Hypoallergenic" Labels

Plaintiffs' deceptive practices, false advertising, unfair competition, and common law claims are also based on allegations that the Product falsely indicates it is free of oxybenzone and is hypoallergenic. Plaintiffs contend these statements are untrue because the Product contains benzophenone.

Even if plaintiffs' claims were not preempted by the FDCA, defendants argue plaintiffs fail to state a claim based on these statements because the presence of benzophenone is irrelevant to the Product's free of oxybenzone labeling and plaintiffs fail plausibly to allege benzophenone is an allergen.

The Court agrees.

First, plaintiffs allege the Product label is misleading because it states it is "free of oxybenzone," yet the Product contains benzophenone. (SAC ¶ 31). However, plaintiffs only allege that benzophenone is present in the Product, not oxybenzone.

Although plaintiffs contend benzophenone-3, an FDA-approved sunscreen ingredient, is the same as oxybenzone, they clarify "there are several distinct benzophenone compounds" (SAC ¶ 2 n.1), and nowhere in the SAC do they allege the Product contains benzophenone-3. In

fact, plaintiffs allege the benzophenone in the Product is not FDA approved, which implies the Product contains a completely different compound than benzophenone-3/oxybenzone. Accordingly, plaintiffs have not adequately pleaded that the "free of oxybenzone" label is false or misleading, and their deceptive practices, false advertising, unfair competition, and common law claims that arise from this labeling must be dismissed.

Second, plaintiffs argue the Product's label is false and misleading because it states the Product is "'Hypoallergenic & Gentle,' but it contains benzophenone which is widely regarded as an allergen and skin irritant." (SAC ¶ 35). In support of these allegations, plaintiffs cite two studies.[3] The first study discusses the presence of benzophenone-3 in sunscreens and its allergenic properties. See Ashley R. Heurung, et al., Benzophenones, 25 Dermatitis 3 (2014), available at https://journals.lww.com/dermatitis/Fulltext/2014/01000/Benzophenones.2.aspx. The study specifically states, "the amount of benzophenone-3 used in US sunscreens is more than all other benzophenones combined," and discusses examples of adverse reactions to the benzophenone-3 compound in particular. Id. However, as discussed above, the SAC alleges the Product contains a benzophenone other than the FDA-approved benzophenone-3/oxybenzone. While the study further discusses benzophenone-4 as being present in some sunscreens and having allergenic properties, it also notes, "the literature regarding adverse reactions to [benzophenones-8 and -10] is scarce" and "[t]he remainder of the benzophenones has not been documented in the literature as eliciting allergic contact dermatitis." Id. at 8 (emphasis added).

[3] Because the SAC makes several references to the two studies discussed in this section, the Court concludes that both documents, although not attached as exhibits to the SAC, are incorporated by reference. See DiFolco v. MSNBC Cable L.L.C., 622 F.3d at 111. Moreover, it is clear the SAC "relies heavily on [their] terms and effect" because they are integral to the allegation that the Product is not hypoallergenic. Id.

The SAC does not specifically identify which benzophenone compound is present in the Product. In light of the study's comment regarding the predominance of benzophenone-3 in sunscreen and the lack of documented reactions to most benzophenone compounds, the Court cannot reasonably infer from the SAC that the potentially allergenic benzophenones are present in the Product.

Elsewhere in the SAC, plaintiffs cite another scientific study to support the allegation that benzophenone "is associated with a wide range of toxicities, including genotoxicity, carcinogenicity, and endocrine disruption." (SAC ¶ 37). See C.A. Downs, et al., Benzophenone Accumulates over Time from the Degradation of Octocrylene in Commercial Sunscreen Products, 34 Chemical Research in Toxicology 1046 (2021). However, this study, which examines benzophenones in sunscreen, does not establish or imply that benzophenone is an allergen, nor does it discuss adverse reactions from exposure to benzophenone.

Accepting all well-pleaded allegations in the SAC as true and drawing all reasonable inferences in plaintiffs' favor, the Court concludes they do not plausibly allege the benzophenone in the Product is an allergen. That is, plaintiffs do not identify which benzophenone is in the Product, and the studies cited in support either do not substantiate that benzophenone is an allergen or primarily focus on a type of benzophenone that, according to the SAC, is not present in the Product. Finally, the Heurung study notes other benzophenones are not prevalent in sunscreen and there have not been many—if any—documented allergic reactions to them. Thus, plaintiffs fail plausibly to allege the Product's labeling as "hypoallergenic" is false or misleading.[4]

[4] Plaintiffs also allege defendants' statements that the Product is "dermatologically tested," and "gentle on baby's skin" are false and misleading because the Product contains benzophenone. (Pl. Opp. at 6). For the same reasons plaintiffs fail plausibly to plead the

Accordingly, plaintiffs' deceptive practices, false advertising, unfair competition, and common law claims must be dismissed to the extent they arise from the Product's free of oxybenzone and hypoallergenic labeling.[5]

CONCLUSION

The motion to dismiss is GRANTED.

The Clerk is instructed terminate the motion (Doc. #48) and close this case.

Dated: November 15, 2022
White Plains, NY

SO ORDERED:

Vincent L. Briccetti
United States District Judge

Product is hypoallergenic, plaintiffs fail to state a claim that these statements are false or misleading.

[5] Because the Court concludes each of plaintiffs' claims must be dismissed, the Court does not reach the question of whether plaintiffs have standing to seek injunctive relief regarding those claims. Generally, when a defendant moves to dismiss for lack of subject matter jurisdiction and "on other grounds, the court should consider the Rule 12(b)(1) challenge first since if it must dismiss the complaint for lack of subject matter jurisdiction, the accompanying defenses and objections become moot and do not need to be determined." Rhulen Agency, Inc. v. Ala. Ins. Guar. Ass'n, 896 F.2d 674, 678 (2d Cir. 1990). Here, however, defendants only assert a standing challenge to plaintiffs' ability to seek injunctive relief, which would not moot plaintiffs' accompanying defenses and objections.